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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2010-0023]

Shiga Toxin-Producing Escherichia coli (STEC) in Certain Raw Beef Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it has completed and is making available its analysis on the estimated costs and benefits associated with the implementation of its non-O157 STEC testing on beef manufacturing trimmings and the costs and benefits associated with the potential expansion of its non-O157 STEC testing to ground beef and ground beef components other than beef manufacturing trimmings. In addition, FSIS is responding to comments that it received on the previous cost benefits analysis.

DATES: To receive full consideration, comments should be received by [INSERT DATE 60 DAYS AFTER PUBLICATION].

Addresses: FSIS invites interested persons to submit comments on this notice and the cost benefit analysis. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS 2010-0023. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

DOCKET: For access to background documents or comments received, go to the FSIS Docket Room at Patriot Plaza 3, 355 E Street, SW., Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D.,
Assistant Administrator, Office of Policy and Program
Development, Food Safety and Inspection Service, U.S. Department
of Agriculture; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On September 20, 2011, FSIS announced in the [Federal Register](#) its determination that raw, non-intact beef products or raw, intact beef products that are intended for use in raw, non-intact product, that are contaminated with Shiga toxin-producing Escherichia coli (STEC) O26, O45, O103, O111, O121, or O145 are adulterated within the meaning of 21 U.S.C. 601(m)(1) (76 FR 58157; Sep. 20, 2011). In support of its determination, the Agency cited evidence of the STEC organisms' high pathogenicity, low infectious dose, transmissibility from person to person, and thermal resistance high enough for them to survive ordinary cooking (76 FR 51858-51859). FSIS stated that raw, non-intact beef products that are contaminated with these STEC are also unhealthful and unwholesome (under 21 U.S.C. 601(m)(3)) (76 FR 58159).

In this 2011 [Federal Register](#) notice, FSIS included an estimate of costs and benefits of testing for non-O157 STEC in all non-intact beef product subject to Agency testing (76 FR 58157; Sept. 20, 2011, at 58162-58164). The Agency asked for

comments on its plans for implementing the program, including cost estimates (76 FR 58164), which included costs to FSIS laboratories for analyzing trim samples for non-O157 STEC (approximately \$204,050 to \$338,270 per year in 2010 dollars), cost of additional establishments testing for non-O157 (about \$12.3 million to \$16.4 million per year), and the loss to the industry from diverting the contaminated products (about \$12.1 to \$16.1 million per year). FSIS also announced in this notice its plan to conduct a new "checklist" survey of its field inspection personnel who are stationed in beef slaughter and processing establishments.

FSIS implemented a verification sampling and testing program for the six adulterant non-O157 STEC in raw beef manufacturing trimmings on June 4, 2012, as announced in a 2012 Federal Register notice ([77 FR 9889](#); Feb. 2012). The Agency also announced ([75 FR 31975](#) at 31976; May 31, 2012) that it would update and revise the September 20, 2011, economic analysis, respond to comments received on the analysis, and assess the economic effects of testing for the specified STECs on raw beef manufacturing trimmings, other raw ground beef components, and ground beef. FSIS also announced that when the economic analysis was complete, the Agency would announce its availability, request comments on it, assess the comments, and make any necessary changes to the analysis before finalizing the

analysis and expanding FSIS testing to include other raw ground beef components and ground product.

Summary of the Economic Analysis

FSIS has estimated the cost to the regulated industry and FSIS associated with the implementation of its non-0157 STEC testing on beef manufacturing trimmings since June 2012, based on Agency testing data and information collected through the FSIS 2013 Pathogen Controls in Beef Operations Survey. This survey is available at:

[[http://www.fsis.usda.gov/wps/wcm/connect/184a3baa-2f73-4651-8aba-68124580f4e0/Pathogen Controls in Beef Operations Survey.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/184a3baa-2f73-4651-8aba-68124580f4e0/Pathogen_Controls_in_Beef_Operations_Survey.pdf?MOD=AJPERES)]

The survey report is at:

[[http://www.fsis.usda.gov/wps/wcm/connect/6d37a1fc-a3e1-40b6-90cc-719bdb391522/STEC Survey Comments Summary.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/6d37a1fc-a3e1-40b6-90cc-719bdb391522/STEC_Survey_Comments_Summary.pdf?MOD=AJPERES)],

and the cost-benefit analysis is at:

[<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notice>]. The cost for the

current testing of beef manufacturing trimmings (including Agency and the industry testing) is about \$1.37 million. If the Agency expands the testing to bench trim, other components, and raw ground beef, it will add another \$1 million to the cost and bring up the grand total to about \$2.37 million. Of the \$2.37 million, \$1.38 million is for FSIS and \$0.99 million for the industry.

FSIS also assessed the benefits associated with the new testing. Benefits would accrue from reduced illnesses and deaths, reduced outbreak-related recalls, and improved business practices. FSIS has concluded that the benefits accruing to industry, Government, and consumers from this new testing policy will result in net economic benefits. However, FSIS was not able to quantify the benefits of expanding the testing.

Summary of the New Checklist Survey Results:

In May-July 2013, FSIS conducted the checklist survey entitled, "The Pathogen Controls in Beef Operations Survey." The purpose of the survey was to gather information on the controls that beef slaughtering and processing establishments have in place to reduce STEC and Salmonella contamination. The survey questions covered a wide range of topics, including establishment pre-harvest management controls, establishment sanitary dressing procedures, establishment carcass sampling and testing, establishment use of high event periods, information on which beef products are produced at particular establishments, and controls that establishments use to address STEC. FSIS sent surveys to inspectors in 486 establishments out of a total of approximately 2,300 beef slaughter or beef processing establishments to collect the information. The survey results related to non-O157 STEC testing include that about 29 percent of the beef establishments

reassessed their HACCP plans for raw beef products based on FSIS's new non-O157 STEC policy, and about 43 percent of the establishments that tested for non-O157 STEC took more than one action (such as confirmatory testing following presumptive positive results or cooking) with products that screened positive. FSIS used the survey results and an updated risk assessment to develop the updated economic analysis.

Response to Comments on the 2011 Federal Register notice

Comment: A trade association stated that the FSIS verification sampling and testing for non-O157 STEC will lead to additional costs for taxpayers and consumers because of increased testing and destruction or diversion of meat.

Response: FSIS recognizes that FSIS testing will likely result in additional costs to establishments. The Agency understands that the industry is likely to transfer some of its costs to consumers. The Agency has determined, however, that the benefits resulting from reduced illness and deaths, reduced outbreak-related recalls, and improved business practices justify the costs.

Comment: A trade association stated that FSIS underestimated the cost to the Agency and to the industry of implementing this new program. According to the commenter, the true cost of Agency testing, including the cost for testing ground beef, would total \$1,170,564 per year in additional

expenses. The commenter also stated that adding the costs attendant on a "for-cause Food Safety Assessment," which FSIS conducts when ground beef is confirmed to contain STEC, would add an additional \$854,000. According to the comment, FSIS has grossly underestimated the cost of implementing this policy testing.

Response: The Agency has updated the cost estimate to include the costs of expanding testing to raw ground beef products and other raw ground beef components (other than manufacturing trimmings). FSIS found that there will be additional benefits, as well as additional costs, should the Agency begin testing additional product for non-O157 STEC. As mentioned in the Summary of Economic Analysis, the cost for the current testing of beef manufacturing trimmings (including Agency and the industry testing) is about \$1.37 million. If the Agency expands the testing to bench trim, other components, and raw ground beef, it will add another \$1 million to the cost and bring the grand total to about \$2.37 million. Of the \$2.37 million, \$1.38 is for FSIS and \$0.99 for the industry.

FSIS also estimated the benefits associated with the new testing policy. Benefits would accrue from reduced illnesses and deaths, reduced outbreak-related recalls, and improved business practices. The Agency still concludes that the costs

are low for new testing that is warranted, and that the benefits justify the costs.

Comment: A trade association stated that the Agency grossly miscalculated the costs to industry and made seriously flawed assumptions in its cost analysis when it concluded that only 33 percent of beef slaughter establishments test for E. coli O157:H7. The trade association stated that the better measure for this analysis would be to use the data in Table 5.2.10 in FSIS' 2007 checklist study - "Testing of Source Materials for 03B Establishments."

Response: The Agency has updated the cost analysis adopting a slightly different approach with information from our 2013 Pathogen Controls in Beef Operations Survey. Thus, there is no reason to use the outdated data from the 2007 checklist study any more. Details are in the updated cost-benefit analysis.

Comment: A trade association stated that FSIS estimated in the 2011 Federal Register notice that approximately 20 percent of establishments were testing for non-O157 STEC and did not adequately support that estimate. The comment further stated that the Agency failed to account properly for added laboratory costs for the industry. The commenter stated that industry analysis estimates added laboratory costs to the industry to range from \$2.5 million to almost \$2.9 million annually.

Response: The Agency has updated the cost analysis using information from the 2013 Pathogen Controls in Beef Operations Survey and used a slightly different approach from the approach used in the earlier estimate. This approach is based on the number of samples tested by the industry and accounts for the added laboratory costs as well. The commenter did not provide information on how the laboratory costs of \$2.5 million to \$2.9 million were derived. As is explained in the revised cost benefit analysis, FSIS estimates that these costs to industry would be \$0.99 million, and these costs to FSIS would be \$1.38 million.

Comment: A trade association commented that the Agency's estimate of total beef trimmings production - 2.05 billion pounds - is inaccurate. The trade association claimed that, for the year ending June 30, 2010, the industry produced 6.96 billion pounds of ground beef, and that, since ground beef is only produced from raw ground beef components, i.e., trimmings, the more realistic volume of beef trimmings is also approximately 6.96 billion pounds. Additionally, the trade association stated that because the amount of trimmings is approximately 3.4 times greater than the Agency estimate, a more accurate range of the cost of diverted products is approximately \$13.24 million to \$17.65 million dollars. A foreign government stated that the value of product that is confirmed positive and

diverted for cooking will be reduced by approximately 70 to 75 percent.

Response: The Agency has updated the cost analysis and does not use estimated production volume or the value lost for products diverted for cooking in the updated analysis. In examining the 2013 Pathogen Controls in Beef Operations Survey data, we found that 43 percent of the establishments that tested for non-O157 STEC took more than one action, including proceeding to confirmation testing, cooking, destroying, and others, with products that screened positive. The Agency believes that it is not possible to get the total volume of the products disposed under any of the actions, even if we asked that question, because the actions the establishments choose are often based on their particular circumstances. For example, if the establishment is very confident with its screening test methodology, it will probably cook the products that screen positive subject to available cooking capacity. If the establishment is not confident about its screening methodology, and there is not enough cooking capacity, it will probably proceed to confirmation or destroy the products, depending on the relative costs of conducting confirming tests versus destroying the products. Empirical literature on industry behavior shows that industry behaves strategically to maximize profits or minimize losses.

Therefore, establishments' choice of action with regard to product that screened positive will be based on particular circumstances, and whatever actions an establishment takes, the incentive is to avoid recalls and potential outbreaks at the minimum cost. Furthermore, if industry focused more on using the data from the verification testing conducted by the establishment and FSIS to improve the prevention efforts at slaughter, there would be even less contaminated product to be diverted.

Comment: Several industry commenters stated that the Agency improperly calculates the cost of holding tested product and fails to consider the additional time needed to complete the STEC test through the final stage of confirmation and the other costs attendant thereto.

Response: If industry decides to hold product that screened positive in their own testing until confirmed positive results are attained, then this is a business decision not driven by FSIS. Today, establishments do not typically await a confirmed positive result before taking action on the affected production lot. Industry responds to the screen positive result, as stated by another commenter below. The new non-O157 STEC screen method that FSIS uses takes the same amount of time as the method for E. coli O157:H7. Agency data for FY2013 showed that the screen positive sample rate for non-O157 STEC in

beef manufacturing trimming is only 2 percent. Therefore, the additional cost of holding products because of additional FSIS testing and additional positive samples is likely to be minimal.

Comment: A trade association representing the meat industry stated that there will be more recalls based on testing, and that the Agency's economic analysis failed to consider recalls. The industry, however, estimates that the new testing will result in at least 24 additional recalls annually and perhaps as many as 48 additional recalls. According to the commenter, using Agency data, those added recalls will cost the industry between \$72 million and \$144 million annually.

Response: For FSIS testing, the establishments have to hold products that screened positive, and therefore there should be no recalls. Recalls should only happen when establishments failed to hold positive products from their own testing. Since FSIS started testing in June 2012, there have been only two Class-I recalls associated with raw beef products with non-O157 STEC, and in both cases products were recalled before any illness was reported. These early-stage recalls actually carried the benefit of preventing potential outbreaks and outbreak-related recalls, which are more costly to the industry as well as the consumers and the government. The goal of the new policy is to better ensure that adulterated product does not enter commerce and, hence, will not have to be recalled.

Comment: A trade association representing the meat industry suggested that there will be significant impact on a significant number of small and very small businesses from increased cost of raw materials, holding tested product, resources needed for supporting documentation, validation, and verification that current control programs for O157 are effective against the six additional STEC strains, and from reassessing HACCP plans.

Response: Any increase in the cost of raw materials would be borne by large establishments as well. The Agency believes that the increased cost from holding the tested product because of additional testing and additional positive samples will not be significant because Agency test data for FY 2013 showed that the screen positive sample rate for non-O157 STEC in beef manufacturing trimming is only 2 percent. The cost of documentation and reassessment of HACCP plans will be minimal too, as the small and very small businesses have to reassess their HACCP plans at least annually. Again, a focus on preventing contamination is likely to be more effective than reliance on testing.

Comment: A trade association representing the meat industry has estimated that the cost per test is \$19, plus an additional \$9 if the sample is a presumptive positive during the screen. An estimate for final confirmatory testing was not

completed by the commenter, as the commenter noted that the beef industry generally makes disposition decisions based upon potential positive results.

Response: The cost per test is more complicated than just one dollar figure. There are many methodologies available to the industry, and some establishments use different methodologies for different time-periods (such as high-prevalence season and other time-periods). For those establishments that are already testing for E. coli O157:H7, adding non-O157 will, in most cases, involve switching to new test kits. Market information and Agency expert opinion indicate that the new test kits will only cost about \$1 or \$2 more per test. If an establishment has to contract out to a different laboratory for non-O157 STEC analysis, we used \$30 for average cost per test based on the cost of FSIS testing methodology, which is available in the market for the industry.

Comment: Some countries exporting beef that commented have estimated the direct cost increase to be around \$2.4 million per annum for new non-O157 STEC testing. Three commenters from Australia stated that the costs will be significant; two of them said that the cost of testing, storage, and documentation could amount to AUD 1.8 million per annum. One commenter from another country stated that having to test United States-destined

trimmings for non-O157 STEC as well as for E. coli O157:H7 would impose an additional multi-million dollar cost burden.

Response: FSIS does not require foreign establishments to test, just as we did not require domestic establishments to test. The foreign establishments, as well as the U.S. establishments, have many alternatives to control for non-O157 STECs. It is the foreign establishments' business decision as to what control measure(s) will be the most cost-effective for them to adopt. FSIS testing policy does not create any unfair burden on the foreign establishments.

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Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce it on-line through the FSIS Web page located at:

<http://www.fsis.usda.gov/federal-register> .

FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/subscribe> . Options range from recalls, export information, regulations,

directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done, at Washington, D.C. November 14, 2014.

Alfred V. Almanza,
Acting Administrator.

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